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PTO/SB/08A (10-01)

Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

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Sheet 1 of 2

Complete If Known

Application Number	09/219,736 09/886,79
Filing Date	12/22/1998
First Named Inventor	Thomas E. Tarara et al.
Art Unit	1615
Examiner Name	R. Bawra
Attorney Docket Number	2054.00

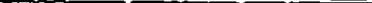
U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. 1	Document Number Number - Kind Code ² (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
YEP	AA	US-4571334	02/18/1986	Yoshida et al.	—
YAL	AB	US-4765987	08/23/1988	Bonte et al.	—
LAI	AC	US-5032585	07/16/1991	Lichtenberger	—
	AD	US-5262405	11/16/1993	Gimod-Vaquez et al.	—
	AE	US-5299566	04/05/1994	Davis et al.	
	AF	US-5451569	09/19/1995	Wong et al.	
	AG	US-5527521	06/18/1996	Unger et al.	
	AH	US-5542935	08/06/1996	Unger et al.	—
	AI	US-5569448	10/19/1996	Wong et al.	
	AJ	US-5648095	07/15/1997	Illum et al.	—
	AK	US-5656297	08/12/1997	Bernstein et al.	
	AL	US-5667808	09/16/1997	Johnson et al.	
	AM	US-5698537	12/16/1997	Pruss	—
	AN	US-5776496	07/07/1998	Violante et al.	—
	AO	US-5853698	12/29/1998	Straub et al.	
	AP	US-5853752	05/29/1998	Unger et al.	—
	AQ	US-5853763	12/29/1998	Tice et al.	—
	AR	US-5925334	07/20/1999	Rubin et al.	—
	AS	US-5955143	09/21/1999	Wheatley	—
	AT	US-5985309	11/16/1999	Edwards et al.	—

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Examiner Signature:  Date: 12/2/02

Signature _____ Considered _____

¹ EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 509. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.
¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 601.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here.

English language Translation is attached.
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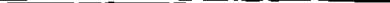


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PTO/SB/08A (10-01)

Substitute for form 1449APTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>				Application Number Filing Date First Named Inventor Art Unit Examiner Name	09/219,739 12/22/1998 Thomas E. Tarara et al. 1615 R. Bawa
Sheet	2	of	2	Attorney Docket Number	
				0054.00	

Examiner Signature		Date Considered	12/02/02
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS

Examiner
Signature

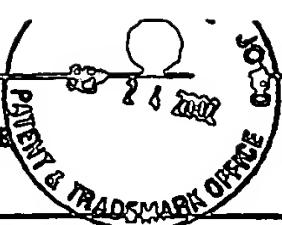
Date
Considered

12/2/02

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¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

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FORM PTO-1449 U.S. DEPARTMENT OF COMMERCE PATENT & TRADEMARK OFFICE 										ATTY DOCKET NO.	APPLICATION NO.		
										0054.10	09/886,296		
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (USE SEVERAL SHEETS IF NECESSARY)										APPLICANT			
										Tarara et al.			
										FILING DATE	OCT 16 2001		
										6/21/2001	6/21/2001		

EXAMINER INITIAL	U.S. PATENT DOCUMENTS										CLASS	SUBCLASS	FILING DATE
	D N	O U	C M	U D	M E	E R	N T	DATE		NAME			
Y	5	3	0	8	6	2	0	A	5/1994	Yen	RECEIVED		
	5	5	6	2	6	0	8	A	10/1996	Sekins et al.	SEP 27 2002		
	5	6	1	6	3	1	1	A	4/1997	Yen			
	5	6	7	3	6	8	6	A	10/1997	Villax et al.	TECH CENTER 1600/2900		
	5	6	7	6	9	2	9	A	10/1997	Akehurst et al.			
✓	5	8	2	9	4	3	5	A	11/1998	Rubaamen et al.			
Y	5	8	5	5	9	1	3	A	1/1999	Homes et al.	424	489	
Y	5	8	7	4	0	6	4	A	2/1999	Edwards et al.			
Y	6	0	4	1	7	7	7	A	3/2000	Faithful et al.	128	200.24	

EXAMINER INITIAL	FOREIGN PATENT DOCUMENTS										CLASS	SUBCLASS	TRANSLATION YES
	D N	O U	C M	U D	M E	E R	N T	DATE		COUNTRY			
Y	0	2	7	4	4	3	1	A2	7/1988	EPO			
	0	3	7	2	7	7	7	A2	6/1990	EPO			
	0	6	1	1	5	6	7	A1	8/1994	EPO			
✓	9	6	1	9	1	9	8		6/1996	WO			
Y	9	7	3	6	5	7	4		10/1997	WO			
Y	9	7	3	6	5	7	8		10/1997	WO			

EXAMINER INITIAL	OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PERTINENT PAGES, ETC.)
	Dallamry et al. "Hollow Porous Particles in Metered Dose Inhalers" Pharm Research 17(2): 168-174 (2000).
Y	Ahneek et al. "The Molecular Basis of Moisture Effects on the Physical and Chemical Stability of Drugs in the Solid State" Int. J. of Pharmaceutics 62: 87-95 (1990).
	Altantek et al. "Ca ²⁺ Binding to Phosphatidylcholine Bilayers As Studied by Deuterium Magnetic Resonance. Evidence for the Formation of a Ca ²⁺ Complex with Two Phospholipid Molecules" Biochemistry 23: 3913-3920 (1984).
	Babinova et al. "Dextran Enhances Calcium-Induced Aggregation of Phosphatidylserine Liposomes: Possible Implications for Exocytosis" Physiol Res 48(4): 319-321 (1999).
✓	Buckton et al. "The Use of Gravimetric Studies to Assess the Degree of Crystallinity of Predominantly Crystalline Powders" Int. J. of Pharmaceutics 123: 265-271 (1995).
Y	Buldt et al. "Neutron Diffraction Studies on Phosphatidylcholine Model Membranes" J. Mol. Biol. 134: 673-691 (1979).

EXAMINER	Y	DATE CONSIDERED	12/2/02
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*EXAMINER: INITIAL IF CITATION CONSIDERED, WHETHER OR NOT CITATION IS IN CONFORMANCE WITH MPEP 609. DRAW LINE THROUGH CITATION IF NOT IN CONFORMANCE AND NOT CONSIDERED. INCLUDE COPY OF THIS FORM WITH NEXT COMMUNICATION TO APPLICANT.

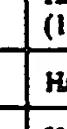
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FORM PTO-1449 U.S. DEPARTMENT OF COMMERCE PATENT & TRADEMARK OFFICE - INFORMATION DISCLOSURE STATEMENT APPLICANT (USE SEVERAL SHEETS IF NECESSARY)	ATTY DOCKET NO. 0054.10	APPLICATION NO. 09/886,296
	APPLICANT Tarara et al.	
	FILING DATE 6/21/2001	GROUP -1616

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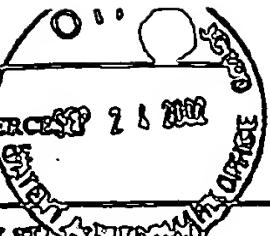
SEP 27 2002

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EXAMINED INITIAL		OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PERTINENT PAGES, ETC.)
		Gordon et al. "Ideal Copolymers and the Second-Order Transitions of Synthetic Rubbers. I. Non-Crystalline Copolymers" <i>J. Appl. Chem.</i> 2: 493-500 (Sept., 1952).
		Hancock et al. "Characteristics and Significance of the Amorphous State in Pharmaceutical Systems" <i>J. of Pharmaceutical Sciences</i> 86(1): 1-12 (Jan., 1997).
		Hancock et al. "The Relationship Between the Glass Transition Temperature and the Water Content of Amorphous Pharmaceutical Solid-Phase Research" 11(4): 471-477 (1994).
		Hauser et al. "Comparative Structural Aspects of Cation Binding to Phosphatidylserine Bilayers" <i>Biochim Biophys Acta</i> 813: 343-346 (1985).
		Hauser et al. "Interactions of Divalent Cations with Phosphatidylserine Bilayer Membranes" <i>Biochemistry</i> 23: 34-41 (1984).
		Huster et al. "Investigation of Phospholipid Area Compression Induced by Calcium-Mediated Dextran Sulfate Interaction" <i>Biophys J.</i> 77(2): 879-887 (Aug., 1999).

12/2/02

*EXAMINER: INITIAL IF CITATION CONSIDERED, WHETHER OR NOT CITATION IS IN CONFORMANCE WITH MPEP 699; DRAW LINE THROUGH CITATION IF NOT IN CONFORMANCE AND NOT CONSIDERED.
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FORM PTO-1449
U.S. DEPARTMENT OF COMMERCE
PATENT & TRADEMARK OFFICE

SHEET 4

FORM PTO-1449 U.S. DEPARTMENT OF COMMERCE PATENT & TRADEMARK OFFICE <i>SEARCHED</i> <i>INDEXED</i> <i>MAILED</i>	ATTY DOCKET NO. 0054.10	APPLICATION NO. 09/886,296
INFORMATION DISCLOSURE STATEMENT APPLICANT (USE SEVERAL SHEETS IF NECESSARY)	APPLICANT Tarara et al.	
	FILING DATE 6/21/2001	GROUP 1616

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SEP 27 2002

TECH CENTER 1600/2000

EXAMINER INITIALS	OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PERTINENT PAGES, ETC.)
	Hunter et al. "Strength of Ca(2+) Binding to Retinal Lipid Membranes: Consequences for Lipid Organization" <i>Biophys J.</i> 78(6): 3011-3018 (June, 2000).
	Jacobson et al. "Phase Transitions and Phase Separations in Phospholipid Membranes Induced by Changes in Temperature, pH, and Concentration of Bivalent Cations" <i>Biochemistry</i> 14(1): 152-161 (1975).
	Kwon et al. "Calcium Ion Adsorption on Phospholipid Bilayers- Theoretical Interpretation" <i>J Jpn Oil Chem Soc</i> 43(1): 23-30 (1994).
	Lis et al. "Adsorption of Divalent Cations to a Variety of Phosphatidylcholine Bilayers" <i>Biochemistry</i> 20: 1771-1777 (1981).
	Lis et al. "Binding of Divalent Cations to Dipalmitoylphosphatidylcholine Bilayers and Its Effect on Bilayer Interaction" <i>Biochemistry</i> 20: 1761-1770 (1981).
	Millqvist-Fureby et al. "Surface Characterisation of Freeze-Dried Protein/Carbohydrate Mixtures" <i>Int J. Pharm.</i> 191: 103-114 (1999).

EXAMINED: INITIAL CITATION CONSIDERED. WHETHER OR NOT CITATION IS IN CONFORMANCE WITH MPEP 607. DRAW LINE THROUGH CITATION IF NOT IN CONFORMANCE AND NOT CONSIDERED. INCLUDE COPY OF THIS FORM WITH NEXT COMMUNICATION TO APPLICANT.

FORM PTO-1449 U.S. DEPARTMENT OF COMMERCE PATENT & TRADEMARK OFFICE SEP 26 2001 PATENT & TRADEMARK OFFICE		ATTY DOCKET NO. 0054.10	APPLICATION NO. 09/886,296
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (USE SEVERAL SHEETS IF NECESSARY)		APPLICANT Tarara et al.	
		FILING DATE 6/21/2001	GROUP 1616

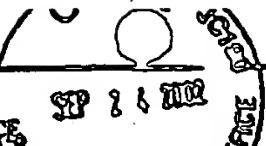
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EXAMINER INITIAL	OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PERTINENT PAGES, ETC.)
	Milqvist-Furby et al. "Spray-Drying of Trypsin - Surface Characterisation and Activity Preservation" <i>Int. J. Pharm.</i> 188: 243-253 (1999).
	Parasassi et al. "Calcium-Induced Phase Separation in Phospholipid Bilayers. A Fluorescence Anisotropy" <i>Cellular and Molecular Bio</i> 32(3): 261-266 (1986).
:	Rebois, M.D. "Activity Coefficients of CaCl_2 and MgCl_2 in the Presence of Dipalmitoylphosphatidylcholine-Phosphatidylserine Vesicles in Aqueous Media" <i>Bioelectrochemistry and Bioenergetics</i> 39: 101-108 (1996).
	Royall et al. "Characterisation of Moisture Uptake Effects on the Glass Transitional Behaviour of an Amorphous Drug Using Modulated Temperature DSC" <i>Int. J. Pharm.</i> 192: 39-46 (1999).
	Saitoh, Koichi. "Determination of Binding Constants of Ca^{2+} , Na^+ , and Cl^- Ions to Liposomal Membranes of Dipalmitoylphosphatidylcholine at Gel Phase by Particle Electrophoresis" <i>Biochim Biophys Acta</i> 1239: 239-248 (1995).
	Seddon, J.M. "Structure of the Inverted Hexagonal (H_1) Phase, and Non-Lamellar Phase Transitions of Lipids" <i>Biochim Biophys Acta</i> 1031: 1-69 (1990). . in particular p. 43-44 and 49-50.

**EXAMINER: INITIAL IP CITATION CONSIDERED. WHETHER OR NOT CITATION IS IN CONFORMANCE WITH MPEP 609, DRAW LINE THROUGH CITATION IF NOT IN CONFORMANCE AND NOT CONSIDERED. DRAFT LIVE COPY OF THIS FORM WITH NEXT COMMUNICATION TO APPLICANT.*

FORM PTO-1449 U.S. DEPARTMENT OF COMMERCE PATENT & TRADEMARK OFFICE 		ATTY DOCKET NO. 0054.10	APPLICATION NO. 09/886,296
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (USE SEVERAL SHEETS IF NECESSARY)		APPLICANT Tarara et al.	
		FILING DATE 6/21/2001	GROUP 1616

EXAMINED INITIAL	OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PERTINENT PAGES, ETC.)
<i>JL</i>	1. Joachim Seelig, <i>Handb. Met.-Ligand Interact. Biol. Fluids: Bioinorg. Chem. & Metal Ion Interactions with Lipids</i> : 698-706 (1995).
	Shah et al. "The Ionic Structure of Sphingomyelin Monolayers" <i>Biochim Biophys Acta</i> 135: 184-187 (1967).
	Shavrin et al. "Cholesterol Affects Divalent Cation-Induced Fusion and Isothermal Phase Transitions of Phospholipid Membranes" <i>Biochim Biophys Acta</i> 946: 405-416 (1988).
	Simha et al. "On a General Relation Involving the Glass Temperature and Coefficients of Expansion of Polymers" <i>J. Chem. Physics</i> 37(5): 1003-1007 (Sept., 1962).
<i>AS</i>	Sugisaki et al. "Calorimetric Study of the Glassy State. IV. Heat Capacities of Glassy Water and Cubic Ice" <i>Bulletin of the Chemical Society of Japan</i> 41: 2591-2599 (Nov., 1968).
<i>Not included</i>	Tetulian, S.A. "Binding of Alkaline-Earth Metal Cations and Some Anions to Phosphatidylcholine Liposomes" <i>Eur. J. Biochem.</i> 170: 413-420 (1987).

EXAMINED *Frank John* DATE CONSIDERED 12/2 102

EXAMINER: INITIAL & CITATION CONSIDERED, WHETHER OR NOT CITATION IS IN CONFORMANCE WITH MPEP 609. DRAW LINE THROUGH CITATION IF NOT IN CONFORMANCE AND NOT CONSIDERED. INCLUDE COPY OF THIS FORM WITH NEXT COMMUNICATION TO APPLICANT.

FORM PTO-1409 U.S. DEPARTMENT OF COMMERCE PATENT & TRADEMARK OFFICE SEARCHED SERIALIZED INDEXED FILED SEP 23 2012 RECEIVED U.S. PATENT AND TRADEMARK OFFICE	ATTY DOCKET NO. 0054.10	APPLICATION NO. 09/886,296
INFORMATION DISCLOSURE STATEMENT APPLICANT (USE SEVERAL SHEETS IF NECESSARY)	APPLICANT Tarara et al.	
	FILING DATE 6/21/2001	GROUP 16.16

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SEP 21 2002

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EXAMINER INITIAL	OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PERTINENT PAGES, ETC.)
JAL	Tatulian, S.A. "Evaluation of Divalent Cation Binding to Phosphatidylserine Membranes by an Analysis of Concentration Dependence Surface Potential" <i>J. Colloid Interface Science</i> 175: 131-137 (1995).
	Verstraeten et al. "Effects of Al(3+) and Related Metals on Membrane Phase State and Hydration: Correlation with Lipid Oxidation" <i>Arch Biochem Biophys</i> 375(2): 340-346 (March 15, 2000).
	Whippa et al. "Growth of Calcium Monohydrate at Phospholipid Langmuir Monolayers" <i>J Cryst Growth</i> 192: 243-249 (1998).
HAW	Yamaguchi et al. "Adsorption of Divalent Cations onto the Membrane Surface of Lipid Emulsion" <i>Colloids and Surfaces B: Biointerfaces</i> 5: 49-55 (1995).

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SHEET 1 OF 1

FORM PTO-1449 U.S. DEPARTMENT OF COMMERCE PATENT & TRADEMARK OFFICE	ATTY DOCKET NO. 0054.10	APPLICATION NO. 09/886,296
INFORMATION DISCLOSURE STATEMENT APPLICANT (USE SEVERAL SHEETS IF NECESSARY)	APPLICANT Tarara et al.	
	FILING DATE 6/21/2001	GROUP 16.6

EXAMINER INITIAL	OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PERTINENT PAGES, ETC.)

EXAMINER	DATE CONSIDERED
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FORM PTO-149 U.S. DEPARTMENT OF COMMERCE PATENT & TRADEMARK OFFICE		SEP 26 2001 PATENT & TRADEMARK OFFICE	ATTY DOCKET NO. 09/886,10	APPLICATION NO. 09/886,296
INFORMATION DISCLOSURE STATEMENT APPLICANT (USE SEVERAL SHEETS IF NECESSARY)		APPLICANT Tarara et al.		
		FILING DATE 6/21/2001	GROUP 1616	

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U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTY. DOCKET NO.	APPLICATION NO.
INFORMATION DISCLOSURE STATEMENT BY APPLICANT		0054.10	09/886,296
(USE SEVERAL SHEETS IF NECESSARY)		APPLICANT Takara et al	
		FILING DATE 6/21/02	GROUP 1616

EXAMINER INITIAL	OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PERTINENT PAGES, ETC.)
JAD	3. Zarif, et al. (1999) Amphotericin B cochleates as a novel oral delivery system for the treatment of fungal infections. Proceedings of the International Symposium on Controlled Release Bioactive Materials, pp. 864-865, XP-002145322

EXAMINER	Reed	DATE CONSIDERED	12/2/02
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